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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CHOWDHURY, IQBAL HOSSAIN

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/502,351	Applicant(s) ZHANG ET AL.	
	Examiner Iqbal Chowdhury, Ph.D.	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1,2 and 8-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5 and 6 is/are rejected.
- 7) ☒ Claim(s) 3,4 and 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/28/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a 371 of PCT/SG02/00011 filed on February 28, 2005.

The preliminary amendment filed on 9/12/2005 is acknowledged. Claim 1 has been amended. Claims 1-17 are pending.

The traversal is on the ground(s) that according to the IPER, there is no lack of unity, however, examiner finds that lack of unity exists because if a product is known then product lacks special technical feature and there is no contribution over the prior art. In addition, examination in the national phase is not bound by the international phase findings.

Applicants argue that claim 1 has been amended to make clearer the technical relationship between the claim groups and to ensure that every claim shares a technical feature with claim 1 directly by inserting SEQ ID NO: 2 and making other claims dependent on claim 1. Applicants also argue that due to the amendment of claim 1 of Groups I, makes all the Groups related to Group I by the special technical feature of SEQ ID NO: 2, which is not persuasive as SEQ ID NO: 2 is not a shared technical feature of all the claims. Many claims of the instant application do not require SEQ ID NO: 2 and thus this is not a special technical feature linking all the groups.

Applicants arguments that at the very least dependent claims should be rejoined with the claims from which they depend as the technical relationship among these claims is clearly

Art Unit: 1652

established is not persuasive as unity of invention is evaluated independent of the manner of claims.

It is acknowledged that polynucleotides encoding the recited polypeptides derived from SEQ ID NO: 1 and said polypeptide are linked by a technical feature. Furthermore, a search for the elected invention would not encompass a search for any other inventions and searching additional inventions would be an undue burden on the Office. As restriction is clearly permissible even among related inventions as defined in MPEP 808 and 35 U.S.C. 121 allows restriction of inventions, which are independent or distinct.

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 1-2, and 8-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in communication filed on 9/12/2005.

Claims 3-7 are under consideration and are being examined herein.

Claim Objections

Claim 7 is objected to because of the recitation "A composition -----", which refers to a previous claim. "A composition ---" should be changed to "The composition----". Appropriate correction is required.

Claims 4 and 7 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 3. When two claims in an application are duplicates or else are so close in content that

Art Unit: 1652

they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 3, 4 and 7 are objected to because these claims are all duplicates. SEQ ID NO: 2 is the protein encoded by nucleotides 1234-3618 of SEQ ID NO: 1 and inherently SEQ ID NO: 2 inactivates AHL, so all the claims are identical. Appropriate corrections are required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions comprising a polypeptide of SEQ ID NO: 2 from *Ralstonia* sp., which inactivates AHL, does not reasonably provide enablement for any composition comprising a single subunit thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 5 and 6 are so broad as to encompass any composition comprising a single subunit of the AHL lactonase encoded by DNA molecule of SEQ ID NO: 1. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of compositions broadly encompassed by the claim. The only use for the claimed proteins asserted within the specification is as an AHL lactonase for the degradation

Art Unit: 1652

of AHL. However, there is no showing in the specification that the individual subunits recited in the instant claims have this activity nor any guidance provided as to how to recreate this activity beyond the addition of the other subunit of SEQ ID NO: 2

The specification does not support the broad scope of the claims which encompass a composition comprising any subunit of a polypeptide which inactivates AHL because the specification does not establish: (A) what additional components of a composition which may be required for the individual subunits to exhibit nor any additional use of the individual subunits.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including a composition comprising a single subunit of an AHL inactivating enzyme. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of any composition of a single subunit having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Allowable Subject Matter

Claims 3-4 and 7 appear to be allowable over the prior art of record but are objected to as they depend upon a rejected claim or due to claim objections.

Conclusion

Status of the claims:

Claims 3-7 are pending.

Claims 3- 7 are rejected.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Iqbal Chowdhury, PhD
Patent Examiner
Art Unit 1652 (Recombinant Enzymes)
US Patent and Trademark Office

Application/Control Number: 10/502,351

Page 7


Art Unit: 1652

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